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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,056	09/07/2005	Yasutoshi Koga	268949US0X PCT	7447

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
WEBB, WALTER E	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
01/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/530,056	KOGA ET AL.	
	Examiner	Art Unit	
	Walter E. Webb	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-20 are pending.

Claims 1-20 are rejected.

Response to Arguments

Objection of claims 5 and 6 under 37 CFR 1.75(c) as being in improper has been withdrawn in light of applicant's amendment. These claims are no longer multiple dependent.

Rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, has been withdrawn in light of applicant amending claims to reflect "treating" instead of "preventing and/or treating."

Applicant's arguments with respect to the 102(b) rejection of claims 1-4 have been considered but are moot in view of the new ground(s) of rejection.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-3 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is maintained with regard to claims 1-3, and now applies to claims 4-20.

Applicant argues that pages 1-6 of the specification describe in detail the terms "clinical symptoms in a disease caused by mitochondrial dysfunction" and "warning

symptom thereof." The examiner disagrees. Pages 1-6 of the specification gives examples of diseases such as MELAS, CPEO, and MERRF, and examples of symptoms, still there is no clear definition for these broad terms such that the artisan would discern the full breadth and scope of what is claimed.

Furthermore, claims 5, 11, 12, 18, and 19 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 5, 11, 12, 18, and 19 further comprise "another mitochondrial function adjuvant." However, there is no written description of this phrase in the specification such that on of ordinary skill in the art would reasonably discern what is meant by "another mitochondrial function adjuvant." Page 8 lists examples of these adjuvants, but this is inadequate for discerning the meaning of the full breadth and scope of this phrase. The present disclosure fails to recite any structural characteristics, chemical formula, name(s) or physical characteristics such that the artisan would readily identify the scope of those compounds encompassed by the phrase "another mitochondrial function adjuvant." Because there is no support for this phrase in the specification, it is not clear that applicant had possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaesemeyer, (US 5,543,430).

Kaesemeyer teaches a therapeutic mixture of L-arginine and nitroglycerin (glyceryl trinitrate). (See Abstract) They teach administration of the mixture to a subject where the subject received 2.5g of L-arginine. (See col. 8, lines 24-29.) They also teach that the mixture of L-arginine includes both the free form of L-arginine and its monohydrochloride form. (See col. 9, lines 34-36.)

In regard to applicant's claims that the composition treats the expression of clinical symptoms in a disease caused by mitochondrial dysfunction, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since the composition of Kaesemeyer is capable of performing the intended use, then it meets the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-10, 12-17, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooke et al., (US 5,891,459).

Cooke teaches a method of improving vascular nitric oxide activity by orally administering L-arginine or L-arginine hydrochloride as a dietary supplement (see claim col. 26 lines 38-50, or claim 1). Cooke also teaches a method where a cereal bar includes a mixture of L-arginine, L-lysine (another nitric oxide-releasing agent), and Vitamin C (see claim 15, col. 28 lines 20-30.) Cooke disclosed an example of the effects of its composition after oral administration of L-arginine at 7g per day per adult

for 2 weeks (see col. 22 lines 40-50). They also teach that L-arginine is administered in combination with its monomer as a hydrochloride salt. (See col. 7, lines 54-57.)

Cooke does not teach treatment of the expression of clinical symptoms in a disease caused by mitochondrial dysfunction or a disease caused by mitochondrial dysfunction.

It would have been obvious to a person of ordinary skill in the art to administer the composition of Cooke in the treatment of the expression of clinical symptoms in a disease caused by mitochondrial dysfunction or a disease caused by mitochondrial dysfunction since the composition of Cooke would serve the same function in the instant application in increasing nitric oxide. Treating the expression of clinical symptoms in a disease caused by mitochondrial dysfunction or a disease caused by mitochondrial dysfunction would be inherent because the same active agent is being administered to the same patient population, and thus must be acting via the same physiological and biochemical mechanisms.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter Webb
Patent Examiner
AU: 1614

ARDIN H. MARSCHEL 1/7/08
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER